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PATENT  
Attorney Docket No. LEX-007

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANTS: Gillies *et al.* CONFIRMATION NO.: 3473  
SERIAL NO.: 09/621,268 GROUP NO.: 1642  
FILING DATE: July 21, 2000 EXAMINER: K. Canella, Ph.D.  
TITLE: Fc Fusion Proteins for Enhancing the Immunogenicity of Protein and Peptide Antigens

**CERTIFICATE OF FIRST CLASS MAILING UNDER 37 C.F.R. 1.8**

I hereby certify that this correspondence, and any document(s) referred to as enclosed herein, is/are being deposited with the United States Postal Service as first class mail, postage prepaid, in an envelope addressed to the Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on this 20th day of November, 2003.

  
Irja Zarembok

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

Submitted herewith are:

1. Transmittal Form (1 page);
2. Fee Transmittal (1 page);
3. A check in the amount of \$180.00;
4. Second Supplemental Information Disclosure Statement (2 pages);
5. Form PTO-1449 (2 pages);
6. References Labeled A59-A74, B94-B104 and C169-C179; and
7. a return receipt postcard.

NOV 24 2003

TRADEMARK OFFICE 821

PATENT

Attorney Docket No. LEX-007

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APPLICANTS: Gillies *et al.*

CONFIRMATION NO.: 3473

SERIAL NO.: 09/621,268

GROUP NO.: 1642

AGING DATE: July 21, 2000

EXAMINER: K. Canella, Ph.D.

Fc Fusion Proteins for Enhancing the Immunogenicity of Protein and Peptide Antigens

Testa, Hurwitz & Thibault, LLP

*Joseph D.*

**FIRST CLASS MAILING UNDER 37 C.F.R. 1.8**

Correspondence, and any document(s) referred to as enclosed  
United States Postal Service as first class mail, postage  
The Commissioner for Patents, P.O. Box 1450, Alexandria,  
November, 2003.

*Irja Zarembok*  
Irja Zarembok

SECURITY FEATURES INCLUDED. DETAILS ON BACK.

11 226045 10 1000390 512 38317

180.00;  
ation Disclosure Statement (2 pages);

74, B94-B104 and C169-C179; and

Pay: One hundred eighty and 00/100

PAY TO THE ORDER OF: Director of U.S. Patent & Trademark Office

Testa, Hurwitz & Thibault, LLP  
125 High Street  
Boston, MA 02110

Fleet Bank, N.A.  
Boston, Massachusetts 02110

Date:

5-39/110

November 18, 2003

THE FACE OF THIS DOCUMENT HAS A COLORED BACKGROUND ON WHITE PAPER



# TRANSMITTAL FORM

Application Serial No.:	09/621,268
Filing Date:	July 21, 2000
First Named Inventor	Gillies
Group Art Unit	1642
Examiner Name	K. Canella, Ph.D.
Attorney Docket No.	LEX-007

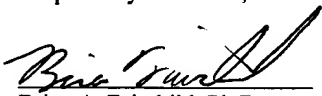
## ENCLOSURES (check all that apply)

- |   |  |   |
|---|--|---|
| <input checked="" type="checkbox"/> Fee Transmittal Form<br><input checked="" type="checkbox"/> Check Attached<br><input type="checkbox"/> Copy of Fee Transmittal Form<br><input type="checkbox"/> Amendment/Response<br><input type="checkbox"/> After Final<br><input type="checkbox"/> Affidavits/declaration(s)<br><input type="checkbox"/> Letter to Official Draftsperson including Drawings [Total Sheets ____]<br><input type="checkbox"/> Extension of Time Request<br><input checked="" type="checkbox"/> Second Supplemental Information Disclosure Statement<br><input checked="" type="checkbox"/> PTO-1449<br><input checked="" type="checkbox"/> Copy of SIDS Citations (A59-A74; B94-B104; C169-C179)<br><input type="checkbox"/> Certified Copy of Priority Document(s) | <input type="checkbox"/> Copy of Notice to File Missing Parts of Application (PTO-1553)<br><input type="checkbox"/> Formal Drawing(s)<br><input type="checkbox"/> Petition Routing Slip (PTO/SB/69) and Accompanying Petition to Convert to a Provisional Application<br><input type="checkbox"/> Power of Attorney (Revocation of Prior Powers)<br><input type="checkbox"/> Terminal Disclaimer<br><input type="checkbox"/> Executed Declaration and Power of Attorney for Utility or Design Patent Application<br><input type="checkbox"/> Small Entity Statement<br><input type="checkbox"/> Request for Refund<br><input type="checkbox"/> After Allowance Communication to Group<br><input type="checkbox"/> Response to Missing Parts/Incomplete Application | <input type="checkbox"/> Appeal Communication to Board of Patent Appeals and Interferences<br><input type="checkbox"/> Appeal Communication to Group ( <i>Appeal Notice, Brief, Reply Brief</i> )<br><input type="checkbox"/> Status Letter<br><input checked="" type="checkbox"/> Return Receipt Postcard<br><input checked="" type="checkbox"/> Certificate of First Class Mailing under 37 C.F.R. 1.8<br><input type="checkbox"/> Additional Enclosure(s) ( <i>please identify below</i> ) |
|---|--|---|

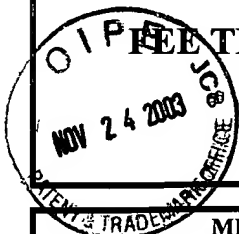
## CORRESPONDENCE ADDRESS

Direct all correspondence to: Patent Administrator  
Testa, Hurwitz & Thibault, LLP  
High Street Tower  
125 High Street  
Boston, MA 02110  
Tel. No.: (617) 248-7000  
Fax No.: (617) 248-7100

## SIGNATURE BLOCK

Respectfully submitted,  
  
Brian A. Fairchild, Ph.D.  
Agent for Applicant  
Testa, Hurwitz & Thibault, LLP  
High Street Tower  
125 High Street  
Boston, MA 02110

Date: November 20, 2003  
Reg. No. 48,645  
Tel. No.: (617) 248-7697  
Fax No.: (617) 248-7100



**FEE TRANSMITTAL**  
FY 2003

Complete if Known

Application Serial Number	09/621,268
Filing Date	July 21, 2000
First Named Inventor	Gillies
Group Art Unit	1642
Examiner Name	K. Canella, Ph.D.
Attorney Docket No.	LEX-007

**METHOD OF PAYMENT**

1. ☒ Payment Enclosed:  
☒ Check ☐ Money Order ☐ Other
2. ☒ The Commissioner is hereby authorized to credit or charge any fee indicated below for this submission to Deposit Account No. 20-0531.  
☐ Required Fees (copy of this sheet enclosed).  
☒ Additional fee required under 37 CFR 1.16 and 1.17.  
☒ Overpayment Credit.
3. ☐ Applicant claims small entity status.

**FEE CALCULATION**

**1. FILING FEE**

**Large Entity**

Fee (\$)	Fee Description	Fee Paid
750	Utility filing fee	
330	Design filing fee	
160	Provisional filing fee	

Number Filed	Number Extra	Rate	Amount
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Total Claims - 20 = x \$ 18.00 =

Independent Claims - 3 = x \$ 84.00 =

☐ Multiple Dependent Claim(s), if any \$280.00 =

TOTAL:

SMALL ENTITY DISCOUNT:

SUBTOTAL (1) (\$)

**2. AMENDMENT CLAIM FEES**

Claims Remaining After Amend.	Highest No. Previously Paid For	Present Extra	Rate	Fee Paid
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Total - = x \$ 18.00 =

Indep. - = x \$ 84.00 =

☐ First Presentation of Multiple Dep. Claim + \$280.00 =

TOTAL: (\$)

SMALL ENTITY DISCOUNT: (\$)

SUBTOTAL (2) (\$)

**FEE CALCULATION (continued)**

**3. ADDITIONAL FEES**

Large Entity Fee (\$)	Small Entity Fee (\$)	Fee Description	Fee Paid (\$)
130	65	Surcharge - late filing fee or oath	
50	25	Surcharge - late provisional filing fee or cover sheet	
130	130	Non-English specification	
2,520	2,520	Request for ex parte reexamination	
110	55	Extension for reply within first month	
410	205	Extension for reply within second month	
930	465	Extension for reply within third month	
1450	725	Extension for reply within fourth month	
1970	985	Extension for reply within fifth month	
320	160	Notice of Appeal	
320	160	Filing a brief in support of an appeal	
280	140	Request for oral hearing	
130	130	Petitions to the Commissioner	
180	180	Submission of Information Disclosure Statement	180.00
750	375	Filing a submission after final rejection (37 CFR 1.129(a))	
750	375	For each additional invention to be examined (37 CFR 1.129(b))	
100	100	Certificate of Correction for applicant's error	
110	55	Submission of Terminal Disclaimer	
Other fee (Specify)			
Other fee (Specify)			

SUBTOTAL (3) (\$ 180.00)

SUBTOTAL (1) \$ 0.00

SUBTOTAL (2) \$ 0.00

SUBTOTAL (3) \$ 180.00

TOTAL (\$ 180.00)

**CORRESPONDENCE ADDRESS**

Direct all correspondence to:  
Patent Administrator  
Testa, Hurwitz & Thibault, LLP  
High Street Tower-125 High Street  
Boston, MA 02110  
Tel. No.: (617) 248-7000  
Fax No.: (617) 248-7100

**SIGNATURE BLOCK**

Respectfully submitted,  
  
Date: November 20, 2003  
Reg. No.: 48,645  
Tel. No.: (617) 248-7697  
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Brian A. Fairchild, Ph.D.  
Agent for the Applicants  
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Boston, MA 02110



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SERIAL NO.: 09/621,268 GROUP NO.: 1642  
FILING DATE: July 21, 2000 EXAMINER: K. Canella, Ph.D.  
TITLE: Fc Fusion Proteins for Enhancing the Immunogenicity of Protein and Peptide Antigens

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**SECOND SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT**

Sir:

In accordance with the provisions of 37 C.F.R. 1.97 and 1.98, Applicants hereby make of record the patents and publications listed on the accompanying Form PTO-1449, and other information contained herein, for consideration by the Examiner in connection with the examination of the above-identified patent application. Copies of the patents and publications are enclosed.

**REMARKS**

In accordance with the provisions of 37 C.F.R. 1.97, this statement is being filed (CHECK ONE):

- ☐ (1) within three (3) months of the **filing date** of a national application other than a continued prosecution application under 37 C.F.R. 1.53(d), or within three (3) months of the **date of entry of the national stage** as set forth in 37 C.F.R. 1.491 in an international application, or before the mailing of the **first Office action** on the merits, or before the mailing of a **first Office action** after the filing of a request for continued examination under 37 C.F.R. 1.114; or
- ☒ (2) after the period defined in (1) but before the mailing date of a **final action** or a **notice of allowance** under 37 C.F.R. 1.311, and
- ☐ the requisite Statement is below, **OR**
- ☒ the requisite fee under 37 C.F.R. 1.17(p), namely **\$180.00**, is included herein, or

- ☐ (3) after the mailing date of a **final action** or **notice of allowance** but before the payment of the **issue fee**, **AND**
- ☐ the requisite Statement is below, **AND**
- ☐ the requisite petition fee under 37 C.F.R. 1.17(p), namely **\$180.00** is included herein.

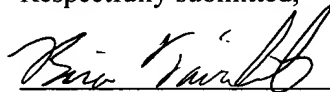
It is respectfully requested that each of the patents and publications listed on the attached Form PTO-1449, and other information contained herein, be made of record in this application.

Applicants believe no additional fee is required at this time. Nevertheless, please charge any additional fees to Deposit Account 20-0531.

Date: November 20, 2003  
Reg. No. 48,645  
Tel. No.: (617) 248-7697  
Fax No.: (617) 248-7100

2713305

Respectfully submitted,



Brian A. Fairchild, Ph.D.

Agent for Applicant

Testa, Hurwitz & Thibault, LLP

125 High Street

Boston, Massachusetts 02110

FORM PTO - 1449

## INFORMATION DISCLOSURE STATEMENT

NOV 24 2003

ATTORNEY DOCKET NO.: LEX-007

APPLICANT(S): Gillies et al.

SERIAL NO.: 09/621,268

FILING DATE: July 21, 2000

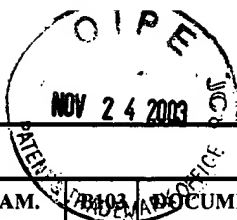
GROUP: 1646

## U.S. PATENT DOCUMENTS

EXAM. INIT.		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB CLASS	FILING DATE IF APPROPRIATE
	A59	5,856,298	1/5/99	Strickland			
	A60	6,617,135	9/9/03	Gillies et al.			
	A61	2002/0081664 A1	6/27/02	Lo et al.			10/11/01
	A62	2002/0147311 A1	10/10/02	Gillies et al.			2/9/01
	A63	2002/0193570 A1	12/19/02	Gillies et al.			12/4/01
	A64	2003/0044423 A1	3/6/03	Gillies et al.			3/7/02
	A65	2003/0049227 A1	3/13/03	Gillies et al.			6/29/01
	A66	2003/0105294 A1	6/5/03	Gillies et al.			2/24/99
	A67	2003/0157054 A1	8/21/03	Gillies et al.			5/3/02
	A68	2003/0166163 A1	9/4/03	Gillies			12/4/02
	A69	2003/0166877 A1	9/4/03	Gillies et al.			3/29/02
	A70	6,485,726 B1	11/26/02	Blumberg et al.			
	A71	6,475,717 B1	11/5/02	Enssle et al.			
	A72	6,335,176 B1	1/1/02	Inglese et al.			
	A73	2002/0192222 A1	12/19/02	Blumberg et al.			12/19/02
	A74	2001/0053539 A1	12/20/01	Lauffer et al.			12/20/01

## FOREIGN PATENT DOCUMENTS

EXAM. INIT.		DOCUMENT NUMBER	DATE	COUNTRY CODE	CLASS	SUB CLASS	FILING DATE	ABSTRAC T ONLY	ENGLISH LANG (Y/N)
	B94	WO 01/58957 A2	8/16/01	PCT					Y
	B95	WO 02/02143 A2	1/10/02	PCT					Y
	B96	WO 02/072605 A2	9/19/02	PCT					Y
	B97	WO 02/079232 A2	10/10/02	PCT					Y
	B98	WO 02/079415 A2	10/10/02	PCT					Y
	B99	WO 02/090566 A2	11/14/02	PCT					Y
	B100	WO 03/048334 A2	6/12/03	PCT					Y
	B101	WO 03/077834 A2	9/25/03	PCT					Y



B102 FOREIGN PATENT DOCUMENTS									
EXAM. INIT.	DOCUMENT NUMBER	DATE	COUNTRY CODE	CLASS	SUB CLASS	FILING DATE	ABSTRACT ONLY	ENGLISH LANG (Y/N)	
	B102	WO 02/066514 A2	8/29/02	PCT				Y	
	B103	WO 01/36489 A2	5/25/01	PCT				Y	
	B104	1 088 888 A1	4/4/01	EP				Y	
OTHER ART, JOURNAL ARTICLES, ETC.									
EXAM. INIT.	OTHER DOCUMENTS: (Including Author, Title, Date, Relevant Pages, Place of Publication)								
	C169	Boissel et al., (1993), "Erythropoietin Structure-Function Relationships," <u>The Journal of Biological Chemistry</u> , 268:15983-15993.							
	C170	Wen et al., (1993), "Erythropoietin Structure-Function Relationships: High Degree of Sequence Homology Among Mammals," <u>Blood</u> , 82:1507-1516.							
	C171	Angal et al. (1993), "A Single Amino Acid Substitution Abolishes the Heterogeneity of Chimeric Mouse/Human (IgG4) Antibody," <u>Molecular Immunology</u> , 30:105-108.							
	C172	Bitonti et al. (2002), "Transepithelial Absorption of an Erythropoietin-Fc Fusion Protein After Delivery to the Central Airways," <u>Respiratory Drug Delivery</u> , 8:309-312.							
	C173	Darling et al. (2002), "Glycosylation of Erythropoietin Affects Receptor Binding Kinetics: Role of Electrostatic Interactions," <u>Biochemistry</u> , 41:14524-14531.							
	C174	Fibi et al. (1995), "N- and O-Glycosylation Muteins of Recombinant Human Erythropoietin Secreted From BHK-21 Cells," <u>Blood</u> , 85:1229-1236.							
	C175	Hammerling et al. (1996), "In vitro bioassay for human erythropoietin based on proliferative stimulation of an erythroid cell line and analysis of carbohydrate-dependent microheterogeneity," <u>Journal of Pharmaceutical and Biomedical Analysis</u> , 14:1455-1469.							
	C176	Kitamura et al. (1989), "Establishment and Characterization of a Unique Human Cell Line that Proliferates Dependently on GM-CSF, IL-3, or Erythropoietin," <u>Journal of Cellular Physiology</u> , 140:323-334.							
	C177	Locatelli et al. (2001), "Darbepoetin alfa Amgen," <u>Current Opinion in Investigational Drugs</u> , 2:1097-1104.							
	C178	Spiekermann et al. (2002), "Receptor-mediated Immunoglobulin G Transport Across Mucosal Barriers in Adult Life: Functional Expression of FcRn in the Mammalian Lung," <u>J. Exp. Med.</u> , 196:303-310.							
	C179	Syed et al. (1998), "Efficiency of signalling through cytokine receptors depends critically on receptor orientation," <u>Nature</u> , 395:511-516.							
EXAMINER				DATE CONSIDERED					